5 2 Uniformity Of Mass For Single Dose Preparations

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5 2 Uniformity Of Mass

5.2 Uniformity of mass for single-dose preparations
The deviation of individual net mass from the average net mass should not exceed the limits given below 52 Uniformity of mass for single-dose preparations Average mass of tabletDeviation % Number of tablets less than 80 mg ±100 minimum 18 ±200 maximum 2 80 mg to 250 mg ±75 minimum 18 ±150 maximum 2 more than 250 mg ±50 minimum 18
2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE PREPARATIONS
295 UNIFORMITY OF MASS OF SINGLE-DOSE PREPARATIONS Weigh individually 20 units taken at random or, for single-dose preparations presented in individual containers, the contents of 20 units, and determine the average mass Not more than 2 of the individual masses deviate from the average mass by more than the percentage deviation shown
Final text for revision of The International Pharmacopoeia
suppositories is 5 mg or less or is 5% or less of the total formulation or, in the case of sugar-coated and enteric-coated tablets, where the test for 52 Uniformity of mass for single-dose preparations does not apply, or for certain powders for injections when specified in individual monographs
Cylinder stirring element
Suppositories and pessaries All masses 5 Powders for eye-drops and powders for eye lotions (single-dose) Less than 300 mg 300 mg or more 10 75 * When the average mass is equal to or below 40 mg, the preparation is not submitted to the test for uniformity of mass but to the test for uniformity of content of single-dose preparations (296)
Guidance for Industry

(522) Japanese Pharmacopoeia (JP): 602 Uniformity of Dosage Units, as it appears in the JP Fifteenth Edition (March 31, 2006, The Ministry of Health, Labour and Welfare

2.9.40. UNIFORMITY OF DOSAGE UNITS

of 2 methods: content uniformity or mass variation (see Table 2940-1) The test for content uniformity of preparations presented in dosage units is based on the assay of the individual contents of active substance(s) of a number of dosage units to determine

5.1 Uniformity of content for single-dose preparations

suspensions or suppositories is 5 mg or less or is 5% or less of the total formulation or, in the case of sugar-coated and enteric-coated tablets, where the test for 52 Uniformity of mass for single-dose preparations does not apply, or for powders for injection

INTERNATIONAL PHARMACOPOEIA MONOGRAPH ON ORAL ...

Uniformity of content See the general requirements 51 Uniformity of content of single-dose preparations Single-dose oral powders with a content of active ingredient of less than 5 mg or less than 5 per cent of the total mass comply with the test , unless otherwise specified in the individual monograph

2.9.40. UNIFORMITY OF DOSAGE UNITS - uspbpep.com

uniformity of dosage units by mass variation instead of the content uniformity test on the following condition: the concentration Relative Standard Deviation (RSD) of the active substance in the final dosage units is not more than 2 per cent, based on process validation data and development data, and if there has been regulatory approval

905 - | USP

The uniformity of dosage units specification is not intended to apply to suspensions, emulsions, or gels in unitdose containers intended for topical administration The term “uniformity of dosage unit” is defined as the degree of uniformity in the amount of the drug substance among dosage units

Content Uniformity (CU) testing for the 21st Century: CDER ...

Meeting USP <905> content uniformity with < 5% potency loss may provide reasonable assurance that strengths do not lose order of potency on stability 12 Loss of mass (crumbs) typically 1-2%

Guidelines and Best Practices for Uniformity in Mass Appraisal

Guidelines and Best Practices for Uniformity in Mass Appraisal October 2019 5 The Federal Railroad Revitalization (4-R) Act is found in 49 USCS § 11501 and prohibits discrimination against railroad property Another Federal Act, the TEFRA Act (Tax Equity and Fiscal Responsibility Act of 1982),

905 UNIFORMITY OF DOSAGE UNITS USP34

Stage 6 Harmonization 2 □905□ Uniformity of Dosage Units Official December 1, 2011 in conditions of normal use, and express the results as de-in which the terms are as defined in Table 2 livered dose

Standard on Mass Appraisal of Real Property

Mass appraisal requires complete and accurate data, effective valuation models, and proper management of resources Section 2 introduces mass appraisal Section 3 focuses on the collection and maintenance of property data Section 4 summarizes the primary considerations in valuation methods, including the role of the three approaches to value in

Uniformity of Dosage Units (BP 2011 & USP 34)

Uniformity of Dosage Units (BP 2011, USP 34) Frequently asked questions Q: If uncoated tablet contains 2 drug substances but only one of them

meets the requirement for WV, how can the requirement be met? A: In the case of a two-component tablet, uniformity …

European Medicines Agency

215 If a correction factor is called for when different procedures are used for assay of the preparation and for the Content Uniformity Test, the correction factor should be specified and justified in the application dossier

Weight and content uniformity of lorazepam half-tablets: A …

the content of spilt-halves of lorazepam 25 mg tablets Weight variation and drug content of lor-azepam half-tablets were evaluated according to the European Pharmacopoeia tests Only one indi-vidual mass of the 30 half tablets was outside the limits of 85–115% of the average mass, but since it

The Morphology and Uniformity of Circumstellar OH/H 2 O …

and observed them at different scales to reveal the uniformity of mass loss through different layers close to the star This includes observing nearby masers that trace the molecular shell structure

Mass uniformity of nasal sprays

potent drug is accurate mass uniformity, which we tested The studies followed the instructions for use of the drug products Usually nasal sprays are applied with 2 puffs, one in each nostril

Uniformity of Dosage Units, Part 1: Acceptance Value

label claim (LC) (where M may be x, 985 or 1015% LC) or more than 1015% LC (where M may be x, 985 or T% LC) See United States Pharmacopeia (USP) (1) for more detail The concept of acceptance value must be redefined to remove bias and more closely reflect quality targets This paper describes how this can be done Uniformity of Dosage Units,